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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,637	04/13/2001	Yoshikatsu Kodama	011900-309	3072

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07/29/2003

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/833,637

Applicant(s)

KODAMA ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 27-30.

Claim(s) objected to: 17-21.

Claim(s) rejected: 16 and 22-26.

Claim(s) withdrawn from consideration: 12-15.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The reply filed July 2, 2003 does not resolve the current issues under 35 USC 112, second paragraph. Applicants' response has been fully considered, however, claims 16 and 22-26 are rejected under 35 USC 112, second paragraph.

The following response is made to applicants' reply:

1. Claims 16 and 22-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (U. S. Patent 5,505,955). Peterson et al. teach a glycoprotein, which has a molecular weight of 46 kDa and is isolated upon fractionation of human milk fat globules (column 5, lines 23-35; Example 7), absent factual data to the contrary, is the claimed glycoprotein and has the inherent property of the claimed glycoprotein (claim 16). Therefore, chicken egg or milk is anticipated as a food (claim 24) and a pharmaceutical composition (claim 23) which have the property of the glycoprotein, and as an inhibitor of *Helicobacter pylori* colonization (claim 22). Chicken egg or milk also contains fat which is an inhibitor of gastric acid secretion, therefore chicken egg or milk is anticipated as an inhibitor composition of *Helicobacter pylori* colonization (claim 25) and a pharmaceutical composition (claim 26) which contain the properties of the glycoprotein and fat.

In response, applicants indicate the glycoprotein of the '995 patent does not specifically bind to *Helicobacter pylori* urease because the glycoprotein of the '995 patent is derived from milk fat globules (MFG) and has little inhibitory activity against *Helicobacter pylori* urease adherence to gastric mucosa; and the term "specifically binds" is known in the art, which means a substance binds to a particular partner with high affinity, and the specification has defined the term as "predominantly binding to the urease" (page 9, lines 3-6 and page 20, lines 19-21), thus the glycoprotein of the '995 patent which binds *Helicobacter pylori* urease only weakly cannot be a protein as claimed in the instant application which specifically binds to *Helicobacter pylori* urease. The response has been fully considered, however, the argument is not found persuasive because of the following reasons: The glycoprotein of the '995 patent has inhibitory activity of IC50 values of 324-397 ug/ml against *Helicobacter pylori* urease (Table 1 of Exhibit A, Paper No. 11), which although is higher than those (3.9-4.5 ug/ml) of glycoprotein from bovine milk whey, but by no means it has little inhibition because these values are compatible to porcine gastric mucin (290.2 ug/ml) and in the similar range (<1.0 to 311 ug/ml) labeled for high affinity group of inhibitors (see *Gastroenterology*, 119, 358-367 (2001), Table 1). Therefore, the glycoprotein of the '995 patent can be considered as high affinity inhibitor to *Helicobacter pylori* urease, which means it is specifically binds to *Helicobacter pylori* urease; Regarding the term "specifically binds" being defined as "predominantly binding to the urease", the glycoprotein of the '995 patent also fits to the definition because the glycoprotein has high affinity to *Helicobacter pylori* urease. Therefore, the glycoprotein of the '995 patent cannot be differentiated from the glycoprotein recited in claim 16.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issue under 35 USC 112, second paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
July 24, 2003

Christopher S. F. Low
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